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Michael L. Jordan

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EXAMINER

PORTER, RACHEL L

ART UNIT

PAPER NUMBER

3626

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/772,196

**Applicant(s)**

JORDAN, MICHAEL L.

**Examiner**

RACHEL L. PORTER

**Art Unit**

3626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/5/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-6 and 9-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Notice to Applicant***

1. The communication is in response to the amendment filed 6/5/09. Claims 1, 3-6, 9-17 are pending. Claims 10-17 have been withdrawn from consideration.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/09 has been entered.

***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to a particular machine or apparatus or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981);

*Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter.

There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim patent- eligible. This means the machine or transformation must impose meaningful limits on the method claim's scope to pass the test. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such a data gathering or outputting, is not sufficient to pass the test.

Exemplary claim 1 fails to recite the use of a particular machine or apparatus to perform any of the steps in the recited method. In particular, the steps that are actively recited in the method are "evaluating..."; "determining..." and "selecting...". The current claim language does not indicate that any of the these steps is performed by a particular machine or apparatus. Furthermore, the recitation of the phrase " wherein in response to the determination revealing that at least one of the prescriptions is fillable in a non-automated manner" suggests that the entire method can be performed without a particular machine.

Claims 3-6 contain similar deficiencies and fail to correct the deficiencies of claim 1, and are therefore also rejected.

Regarding claim 9, it is not clear that a particular machine or apparatus is used to perform the steps of the recited method. The currently recited steps of evaluating, selecting printing and applying, inserting, routing ... and determining could be performed by an individual rather an apparatus. Furthermore, the recitation of the phrase " wherein in response to the determination revealing that at least one of the prescriptions is fillable in a non-automated manner" suggests that the entire method can be performed without a particular machine. Therefore claim 9, is also rejected as being directed to nonstatutory subject matter.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1,3-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear which steps the applicant considers to be part of the inventive method. As it is current written, the steps that are actively recited in claim 1 are "evaluating..."; "determining..." and "selecting...". As explained above, the current

claim language does not indicate that any of the these steps is performed by a particular machine or apparatus or using any automation.

Claim 1 further recites " wherein in response to the determination revealing that at least one of the prescriptions is fillable in a non-automated manner..." In particular, it is not clear whether "filling the prescription" is part of the claimed invention or not. Moreover, if applicant considers "filling the prescription" to lie within the scope of the invention, it is not clear which steps/ details are considered "filling the prescription" (as distinct from "evaluating the queue of orders..." ; "selecting the appropriate end user container..." (claim 3); "routing the carrier from a dispensing workstation..." (claim 4)).

Also, the claim language renders unclear the extent to which the prescription filling process is "automated" or "non-automated" in independent claim 1 and in the additional dependent claims. In other words, it is unclear whether the prescriptions are merely put aside for manual review by a pharmacist, while the rest of the method takes place in an automated (e.g. robotic) manner, or if the entire process (evaluating; determining; selecting subset of workstations; putting pills in container,...) are performed in an entirely different (manual) process.

The specification fails to clarify the use of the term "non-automated." The Brief Summary explains that the use of the term "non-automated is meant to include semi-automated as well as manual." (par. 5) The Examiner understands "non-automated" to mean that the method steps are performed without automation.

Claims 3-6 inherit the deficiencies of claim 1 through dependency, and are also rejected.

Regarding claim 9, similar analyses may be applied as those used to reject claims 1, and 3-6.

***Election/Restrictions***

6. Newly submitted claims 10-17 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons provided in the Final Rejection mailed 2/5/09.
7. Applicant's reply/amendment filed on 6/5/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
9. Claims 1, 3-6, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lasher et al (US 5,771,657).

[claim 9] Lasher discloses a method of operating a prescription filling line, comprising:

- evaluating a queue of orders to determine whether one or more within each order is fillable in an automated manner or a non-automated manner; (col. 3, lines 32-59)
- selecting an appropriate sized end user container; (Figures 1-2; col. 4, lines 32-53)
- printing and applying a label to said container; (col. 4, lines 5-67)
- inserting the labeled container into a carrier; (Col. 4, lines 5-15, 54-67; col. 5, lines 13-26 )
- routing the carrier to a prescription filling station; (Figure 2, col. 6, lines 6-46)
- routing the carrier to an imaging workstation; and (Col. 8, lines 23-26; figure 9--An RFID tag reader (imaging workstation) verifies that the correct carriers are in place on the turntable.)
- wherein in response to the determination revealing that at least one of the prescriptions is fillable in a non-automated manner, the method further comprises selecting a second subset of said equipment, the second subset comprises non-automated equipment that includes the pharmacist review workstation. (col. 3, lines 32-59; col. 10, lines 52-60; col. 13, lines 19-47—prescriptions that cannot be filled in an automated manner are diverted to pharmacist station for manual filling and review)



- wherein when said order has been filled by the automated equipment, routing each carrier for said order to a packing workstation without a review by a pharmacist, and (col. 10, lines 50-55; col. 12, lines 52-col. 13, line 3: completed orders with no barcode, crossover or imaging discrepancies are shipped out without pharmacist review)
- wherein when said order has at least one prescription filled by the non-automated equipment, routing each carrier for said order to a pharmacist workstation before routing each carrier to the packing workstation. (col. 13, lines 19-47)

[claim 1] Lasher discloses a method of discriminating between orders, comprising:

- evaluating a queue of orders to determine whether one or more prescriptions within each order is fillable in an automated manner or a non- automated manner; and (col. 3, lines 32-59)
- determining a set of workstations for each prescription based on said evaluating, (col. 3, lines 32-59; col. 10, lines 52-60; col. 13, lines 19-47)
- wherein in response to the determination revealing that at least one of the prescriptions is fillable in an automated manner, the method further comprises selecting a first subset of said-set of workstations that excludes a pharmacist review workstation for reviewing a respective filled order, and col. 10, lines 50-55; col. 12, lines 52-col. 13, line 3: (without pharmacist review/ workstation)

- wherein in response to the determination revealing that at least one of the prescriptions is tillable in a non-automated manner, the method further comprises selecting a second subset of said set workstations that includes a pharmacist review workstation. (col. 13, lines 19-47—manually dispensed and/or packaged)

[claim 3] Lasher discloses the method of claim 1 additionally comprising selecting an appropriate sized end user container (Figures 1-2; col. 4, lines 32-53), printing and applying a label to said container (col. 4, lines 5-67), inserting the labeled container into a carrier (Col. 4, lines 5-15, 54-67; col. 5, lines 13-26 ) and routing the carrier among the first or second subset of workstations. (Figure 2, col. 6, lines 6-46)

[claim 4] Lasher discloses the method of claim 3 wherein said routing includes routing the carrier from a dispensing workstation (Figure 2, col. 6, lines 6-46); to an imaging workstation (Col. 8, lines 23-26; figure 9--An RFID tag reader (imaging workstation) verifies that the correct carriers are in place on the turntable.) and to a capping workstation. (col. 8, lines 1-11)

[claim 5] Lasher discloses the method of claim 4 additionally comprising tracking multiple prescriptions that belong to one order and grouping all the prescriptions that belong to one order for shipping. (col. 10, lines 61-col. 11, lines 6; col. 12, lines 52-col. 13, line 10)

[claim 6] Lasher discloses the method of claim 4 additionally comprising routing the carrier to a packing workstation where a patient specific document is printed and inserted into a labeled bag along with the patient's prescription. (col. 9, lines 1-31)

### ***Response to Arguments***

10. Applicant's arguments with respect to claim 1,3-6, and 9 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chudy et al (US 2004/0088187 A1)-discloses a pharmacy workflow management system with semi-automatic dispensing and validation stations; Rice et al (US 6,892,512) discloses an automated prescription filling and packaging system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./  
Examiner, Art Unit 3626

/C. Luke Gilligan/  
Supervisory Patent Examiner, Art Unit 3626